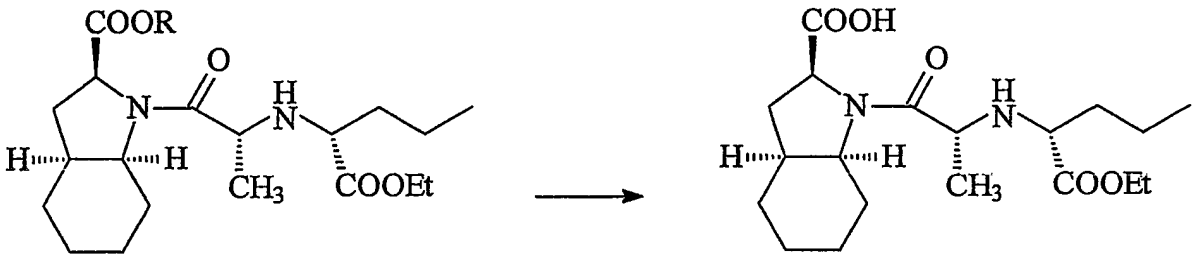
CLAIMS

1 A process for preparing a pharmaceutically acceptable salt of perindopril of formula (I) from a protected precursor compound of formula (II)



(II) (I)

wherein R represents a carboxyl protecting group, which process comprises subjecting a compound of formula (II) to deprotection of the carboxylic group COOR attached to the heterocyclic ring so as to yield the corresponding free acid, which deprotection is carried out in the presence of a base which forms a pharmaceutically acceptable salt with said free acid formed by said deprotection.

2 A process according to claim 1, wherein R represents optionally substituted aralkyl.

3 A process according to claim 2, wherein R represents unsubstituted benzyl.

4 A process according to claim 2, wherein R represents 4-halo substituted, or 4-C_{1-4}alkoxy substituted benzyl.

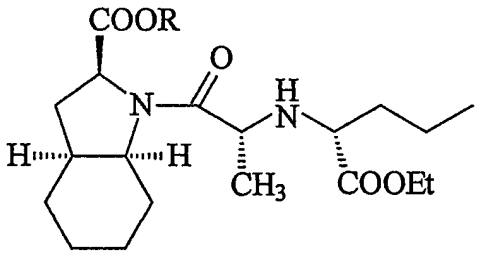
5 A process according to claim 4, wherein R represents 4-Cl benzyl, or 4-methoxy benzyl.

6 A process according to any of claims 1 to 5, wherein deprotection comprises hydrogenolysis in the presence of a noble metal catalyst.

7 A process according to claim 6, wherein the noble metal catalyst comprises palladium-on-chacoal.

8 A process according to any of claims 1 to 7, wherein said base comprises t-butylamine.

9 A process for preparing perindopril t-butylamine from a protected precursor compound of formula (II)



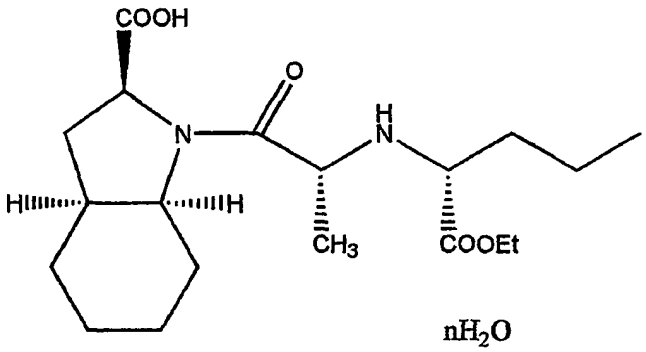
(II)

wherein R represents a carboxyl protecting group, which process comprises subjecting a compound of formula (II) to deprotection of the carboxylic group COOR attached to the heterocyclic ring so as to yield the corresponding free acid, which deprotection is carried out in the presence of t-butylamine so as to form the t-butylamine salt of perindopril.

10 A process according to claim 9, wherein R represents unsubstituted benzyl.

11 A process according to claim 9 or 10, wherein deprotection comprises hydrogenolysis in the presence of palladium-on-chacoal.

12 A process according to any of claims 1 to 11, which further comprises hydrating a pharmaceutically acceptable salt of perindopril obtained by said process so as to yield a pharmaceutically acceptable salt of hydrated perindopril of formula (Ia)



(Ia)

wherein n is an integer of 1 to 5, or a reciprocal of integers 2 to 5.

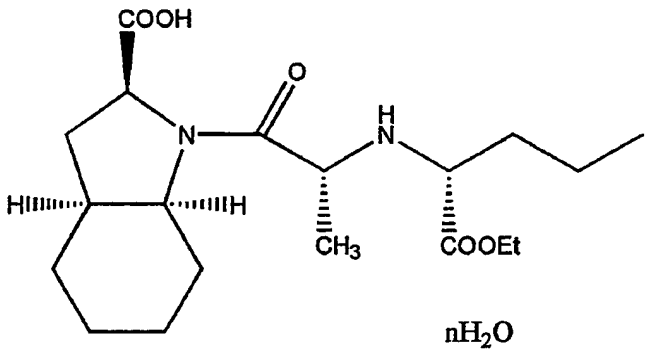
13 A process according to claim 12, wherein n is 1.

14 A process for preparing a monohydrate of a pharmaceutically acceptable salt of perindopril, which process comprises hydrating a pharmaceutically acceptable salt of perindopril so as to yield said monohydrate.

15 A process according to any of claims 12 to 14, wherein perindopril t-butylamine is hydrated to yield perindopril t-butylamine monohydrate.

16 A pharmaceutically acceptable salt of perindopril optionally in hydrated form, prepared by a process according to any of claims 1 to 15.

17 A pharmaceutically acceptable salt of hydrated perindopril of formula (Ia)



(Ia)

wherein n is an integer of 1 to 5, or a reciprocal of integers 2 to 5.

18 A pharmaceutically acceptable salt according to claim 17, where n is 1.

19 A pharmaceutically acceptable salt according to claim 17 or 18, which is the t-butylamine salt.

20 Perindopril t-butylamine monohydrate.

21 Perindopril t-butylamine monohydrate having an X-ray diffractogram, or substantially the same X-ray diffractogram, as set out in Figure 1.

22 Perindopril t-butylamine monohydrate characterised as having an X-ray powder diffraction pattern with characteristic peaks (2θ): 9.5504, 14.8600, 15.7486, 16.5400, 20.0400, 21.0499, 22.0600, 24.1744, 26.3300 and 27.1600.

23 A pharmaceutical composition comprising an effective ACE inhibitory amount of a pharmaceutically acceptable salt of perindopril according to any of claims 16 to 22, together with one or more pharmaceutically acceptable carriers, diluents or excipients therefor.

24 Use of a pharmaceutically acceptable salt of perindopril according to any of claims 16 to 22, in the manufacture of a medicament for inhibiting ACE.

25 A method of inhibiting ACE in a patient in need thereof comprising administering to said patient an effective ACE inhibitory amount of a pharmaceutically acceptable salt of perindopril according to any of claims 16 to 22.